

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS)
LP,)
)
Plaintiff,)
)
v.) Civil Action No. 23-931-CFC
)
XAVIER BECERRA, in his official)
capacity as SECRETARY OF HEALTH)
AND HUMAN SERVICES,)
)
and)
)
CHIQUITA BROOKS-LASURE,)
in her official capacity as)
ADMINISTRATOR OF THE)
CENTERS FOR MEDICARE &)
MEDICAID SERVICES,)
)
Defendants.)

STIPULATED AND ~~PROPOSED~~ ORDER
REGARDING CROSS-MOTIONS FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 7(b) and Local Rule 7, Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca) and Defendants Xavier Becerra et al. jointly move to establish a briefing schedule for the above-captioned matter and for related relief as outlined below.

1. AstraZeneca brought this lawsuit challenging certain aspects of the

drug pricing negotiation provisions of the Inflation Reduction Act of 2022 (IRA), as well as recent guidance issued by the Centers for Medicare & Medicaid Services (CMS).

2. AstraZeneca alleges claims under the Administrative Procedure Act (APA) as well as under the constitution. The parties agree, however, that neither set of claims require discovery, witness testimony, or trial, and instead should be resolved on dispositive motions. The parties further agree that Defendants will not submit an administrative record in this matter. To the extent the parties intend to reference any administrative documents, they will submit them by attaching or linking to them in their briefs. The parties reserve the right to object to any submitted documents

3. One of AstraZeneca's products, Farxiga, was selected by CMS for negotiation under the drug pricing negotiation provisions of the IRA, which lay out a process for potentially establishing a "maximum fair price" (MFP) for Farxiga. The IRA requires manufacturers of selected drugs to respond to CMS's initial offer of an MFP on or before March 2, 2024, at which point AstraZeneca may need to decide whether to accede to the price limitations that it challenges in this lawsuit.

4. The parties have conferred and agreed to a briefing schedule set forth in paragraph 6, below. To avoid the need for preliminary injunction proceedings, and to ensure that the parties are heard on their respective positions before the

negotiations conclude, Plaintiff respectfully requests a decision from this Court on the dispositive motions on or before **March 1, 2024**. Counsel for AstraZeneca had initially proposed a faster briefing schedule than what is set forth below, but is amenable to the schedule set forth below if the Court believes it allows the Court ample time to issue a decision on or before **March 1, 2024**.

5. In the event that the briefing schedule set forth below is not sufficient to permit the Court adequate time to issue a decision by the Target Decision Date of **March 1, 2024**, Plaintiff respectfully requests that the Court convene a status conference or otherwise provide guidance to the parties regarding a briefing schedule that would be sufficient to enable the Court to issue a decision on or before **March 1, 2024**.

6. Given the significant issues raised in this lawsuit, the fact that the entire case will be presented on dispositive motions, and the complicated nature of the regulatory issues involved, the Parties respectfully request the following briefing schedule along with an extension of the default word limits, as set forth below:

AstraZeneca’s motion for summary judgment and supporting brief (7,500 words)	September 26, 2023
Defendants’ combined opposition to AstraZeneca’s motion for summary judgment and brief in support of Defendants’ dispositive motion (combined: 15,000 words)	November 1, 2023

AstraZeneca’s combined opposition to Defendants’ dispositive motion and reply in support of AstraZeneca’s motion for summary judgment (combined: 15,000 words)	December 1, 2023
Defendants’ reply brief (7,500 words)	January 12 ⁵ , 2024
Oral Argument	January <u>31</u> 2024 at <u>9</u> : <u>00</u> a.m.
Target Decision Date	March 1, 2024

7. The parties have agreed that the foregoing schedule is without waiver of either party’s right to seek modification of the case schedule if circumstances warrant.

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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Counsel for Defendants

Dated: September 18, 2023

SO ORDERED this 19th day of September, 2023.



Chief United States District Court Judge